

REMARKS

The Applicants thank the Examiner for his consideration of the case in the telephone interviews of January 8 and 20, 2004 regarding the above named case. At that time, the Applicants explained their logic for responding to the restriction requirement. The Examiner explained his motivation for issuing the restriction and election requirements that he did, and stated that he would consider the arguments presented by the Applicants if put in writing, and reconsider the restriction.

The Examiner stated that upon reading the claims, his first impression was that it was a gene therapy case and that different genes would have different effects and thereby constitute separate inventions.

The Applicants submitted that the instant application does not teach treatment of a specific disease, but instead an improved method of delivery. Essentially, a new syringe was being taught and that the material placed in the syringe had no bearing on the inventiveness of the syringe itself. Therefore, no election is required. The Applicants submit that as the claims are meaningful in the absence of the three groups of claims listed by the Examiner, they do not teach required elements of the invention; therefore, they cannot constitute separate inventions.

The Applicants believe that they were responsive to the requirements for election in the case. The Examiner stated that a single method to increase dwell time, taught in claims 2-6, must be elected. The Applicants elected the method of induction of complete or near complete cardiac arrest and incorporated that limitation into claim 1. The remaining claims, claims 2-4 and 6, were amended to state that the method of claim 1 may further include the steps listed in those claims. Therefore, the methods can be used together and do not constitute a separate invention.

The Applicants did not make an election regarding the permeablizing agent, in claim 7, to be used in the invention, but instead made the statement that all of the

agents were considered equal. The Applicants are aware that this can result in rejection of all of the agents under 103 if a reference teaching one of the agents is found.

The remaining claims in which the Examiner required an election were provisionally cancelled; therefore, no election was made. However, it is conceivable that the genes listed in the claims could be used together. For example, in the case of a deficiency in one of the sarcoglycan subunits, the production of all of the subunits is frequently found to be decreased. It is not uncommon that disruption of the expression or function of a subunit of a complex will alter the expression of all of the members. One explanation for this phenomenon is that the subunits are only stable when they are assembled into a complex. Free subunits are recognized as improperly folded proteins and are destroyed by the cell. It is possible that therapies could be developed for the delivery of expression constructs for expression of multiple sarcoglycan subunits. Therefore, although no specific therapy is taught using a number of genes together, it is not impossible to conceive of a method in which they are used together.

The Applicants further submit that the three groups delineated by the Examiner do not constitute independent groups, but instead, partially overlapping groups. If one makes the assumption that all genes are either structural or functional, Groups I and II respectively, then mutant genes, as defined by Group III must be mutant structural gene or a mutant functional gene. However, the point is essentially moot as the claims have been withdrawn.

The Applicants thank the Examiner for his reconsideration of the matter and request that claims 1-22 and 31 be considered a single invention and be examined as such at this time.

FEES

The Applicants have enclosed a check in the amount of \$55 for an extension of one month time in reply. It is believed that no additional fee is due with this amendment. However, if a fee is due, the Commissioner is hereby authorized to charge any fees to deposit account 02-4070 referencing case number 6627-PA0123.


CONCLUSION

The Applicants believe that this submission is fully responsive and puts the case in proper form for Examination. If the Examiner believes that any issues remain, the Examiner is invited to call the agent, collect, at the number listed below.

Respectfully submitted,

Dated: January 30, 2004

By:


Colleen J. McKiernan, PhD
Agent for Applicant
Registration No. 48,570

GORDON & REES, LLP
1660 Union Street
San Diego, California 92101

Telephone: (619) 238-0999
Facsimile: (619) 238-0062
Docket No.: 6627-PA0123